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MAY 1 8 2004

Surgical Specialties CORPORATION

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS SUBSTANTIAL EQUIVALENCY

Submitter Address:	Surgical Specialties Corporation 100 Dennis Drive Reading, PA 19606
Telephone: Contact Person:	610 404 1000, ext. 2231 Elizabeth Lazaro Regulatory Affairs Specialist
Common / Classification Name:	Surgical Suture Absorbable, Synthetic
Name of Device:	Coated Monoderm™ (Polyglactone 72) Monofilament,Synthetic Absorbable, Dyed and/or Undyed sutures.
Indications for Use:	Indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.
Predicate Devices	Ethicon's Monocryl(Poliglecaprone 25) E caprolactone/Glycolide 510 (k) K930772 U.S. Surgical's Caprosyn (Polyglytone 6211) Glycolide, caprolactone, trimethylene carbonate and lactide. 510 (k) K013671
Device Description:	Coated Monoderm™(Polyglactone 72) suture is a monofilament synthetic absorbable surgical suture prepared from a copolymer of glycolide and e-caprolactone. Coated Monoderm™ suture is prepared by coating Monoderm™ suture with a mixture of caprolactone, glycolide and glycolic acid.
Performance Data:	Physical testing was performed on Monoderm™Coated ,Synthetic, Absorbable sutures to USP 27, including <861>Suture Diameter, <871>Suture Needle Attachment,<881> Tensile Strength. Animal testing was performed for conformance to ISO 10993 for biocompatibility and implant studies to demonstrate rates of tensile strength and mass loss.

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Surgical Specialties CORPORATION

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

Technological Characteristics	Surgical Specialties Corporation's Monoderm™Synthetic, absorbable suture is made from a mixture of Glycolide/e-caprolactone. The material has been well characterized through absorption studies and biocompatibility studies. The product is similar to the predicate devices, Monocryl and Caprosyn, in that they are both made from a polymer blend of synthetic absorbable materials.

Equivalency:
Absorbable, Synthetic, Monofilament

Coated Monoderm sutures are made of a synthetic absorbable suture material, which will dissolve essentially in 91 days.

Caprosyn sutures are made of synthetic absorbable sutures material,which will dissolve essentially in 56 days.

Monocryl sutures are made of synthetic absorbable suture material which will dissolve essentially between 91 and 119 days.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2004

Ms. Elizabeth Lazaro
Regulatory Affairs Specialist
Surgical Specialties Corporation
100 Dennis Drive
Reading, Pennsylvania 19606

Re: K040477
Trade/Device Name: Monoderm™
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorable poly(glycolide/$_L$ lactide) surgical suture
Regulatory Class: II
Product Code: GAM
Dated: February 20, 2004
Received: February 24, 2004

Dear Ms. Lazaro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040477

Device Name: Monoderm™

Indications For Use:

Monoderm™sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040477